IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re- application of LAFONT et al

Serial No. 10/508,739

Group art Unit: 3773
Examiner: GREGORY A ANDERSON

Filed 04/02/2004

For: "Polymer based-stent assembly."

DECLARATION UNDER RULE 132

Hon. Commissioner of Patents and Trademarks
WASHINGTON D.C. 20231

Sir:

I, Tahmer Sharkawi, residing at 1, bis St-Hubery, 34430 St-jean de Védas, France.

Declare and Say:

I am a citizen of Germany residing in France.

I am Doctor in Science (PhD in Material Chemistry) and I am a Project manager working as employee of the company Arterial Remodeling Technologies at the CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE (CNRS).

I am an inventor of the present patent application (Serial No. 10/508,739).

The below observations follow those appearing in my previous declaration dated December 2, 2008.

I read the Office Action dated March 26, 2009 as well as the **Killion** patent (US 6,022,371) and the **Lafont et al.** patent (US 5,957,975).

According to the Examiner in the present Office Action, "Cooling the stent is indicative of the temperature of the stent being forcibly lowered, whereas allowing it to cool indicates that the temperature is allowed to come down at room temperature, thus allowing the stent to cool at much slower pace. Since the rapidity of the cooling process is not claimed, examiner asserts that the step of "cooling the stent" as disclosed by the Killion reference reads on the claimed limitation." (page 5).
The claimed method however specifies "**rapidly cooling** the polymeric cylindrical device **at a temperature below the Tg of the polymer** **to quench** the polymeric cylindrical device".

The expression "**to quench**" is a conventional expression which has a clear meaning for a man skilled in the art of polymer chemistry and material science, and refers to a very rapid decrease of the sample temperature resulting in fixing a structure that corresponds to a higher temperature. Quenching prevents progression of crystal formation through freezing of the polymer structure.
The "Principles of polymerization" (Fourth Edition, 2004, by John Wiley & Sons) further highlights the physical consequences of a rapid cooling: "*Chain folding is maximum for polymers crystallized slowly near the crystalline melting temperature.* ***Fast cooling (quenching)*** *gives a more* ***chaotic crystallization with less chain folding.***".
Finally, the "Six language dictionary of plastics and rubber technology" (A.F. Dorion, London ILIFE books LTD) defines quenching as "*shock cooling of thermoplastics*".

The expression "**Forcibly lowering temperature**" (expression used by the Examiner) is **not equivalent** to "**rapidly cooling** [...] **at a temperature below the Tg of the polymer" (quenching).**

Neither Killion nor Lafont et al. suggest such a quenching step because none of these documents is concerned by the question of **educating** a device made of a polymer.

It is further to note that neither Killion nor Lafont et al. suggest heating the device to a temperature sufficiently above the glass transition temperature (Tg) of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device.
Killion further does not indicate the necessity of **heating** its stent **while maintaining** said stent at a desired final diameter **by mounting it on a solid support**. To avoid the stent collapsing on itself, both Killion and Lafont et al. lay emphasis on the presence of locking means.
Killion states: "*Once cut, the locking stent 10 may be mechanically expanded on a mandrel with* ***locking arms 15 bent such that they are engaged with the notch 17*** *which corresponds to the largest diameter locked position.* ***In its expanded locked form, locking stent 10 may be heat set at about 510°C. for about 2 minutes.*** *Once the locking stent 10 has been heat set and cooled or allowed ro cool, arms 15 may be mechanically disengaged from notches 17 and locking stent 10 then compressed to its unexpanded diameter, ready for mounting on a delivery device.*" (see column 3, lines 39-49).
Lafont et al. state: "*Once expanded, the stents of the present invention are retained in position by friction with the inner wall of the vessel and the second memory imparted by* ***heating*** *the stent* ***prior to expansion. Radial collapse is prevented primarily by engagement of the catch mechanism on the tongue with the inner surface of the head.***" (column 9, lines 32-36).

The educated device according to our invention can be crimped on a balloon and kept crimped without it needing to be restrained. Our device needs to be mechanically expanded, contrary to the Killion stent which need to be restrained by a sheath (on the stent delivery catheter) to prevent its automatic deployment.
In addition, after its mechanical expansion to a final predetermined diameter, our educated device does not necessitate, contrary to the stents described in Killion and Lafont et al., any locking mechanism to avoid negative recoil. It will indeed be advantageously substantially resistant to negative recoil.

As a conclusion, the **Killion and Lafont et al. patents neither describe nor suggest a method as claimed in patent application US 10/508,739.**

The undersigned Declarant declares further that all statements made herein of this own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this day of June 17th, 2009

TAHMER SHARKAWI